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ANTHONY NIEWYK
BAKER & DANIELS
111 EAST WAYNE STREET
SUITE 800
FORT WAYNE, IN 46802

EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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Commissioner for Patents

Attached is Supplemental Examiner's Answer responsive to Appellants' amended appeal (11/17/2003) according to authorization by Board of Patent Appeals and Interferences (Remand to the Examiner, 8/19/2003).

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/331,554
Filing Date: August 23, 1999
Appellant(s): ROUSSEL ET AL.

Anthony Niewyk

For Appellant

Supplemental EXAMINER'S ANSWER

This is in response to the amended appeal brief filed 11/17/2003.

In the amended appeal brief Appellants corrected the Grouping of Claims to indicate that claim 14 is intended to stand or fall by itself and claims 16 and 24 are intended to stand or fall separately from the other claims.

Examiner added response to Appellants' arguments with respect to these claims.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

Claims 13-16, 19-21, 24-26, 29 and 30 are pending and are being appealed.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that the claims 13-16, 19-21, 24-26, 29 and 30 do not stand or fall together and provides reasons as set forth in 37CFR 1.192(c)(7) and (c)(8).

In the amended brief on appeal filed 11/17/2003 Appellants have grouped the claims as follows:

A. Claims 13, 20 and 21 stand or fall together.

B. Claim 14 stands or falls alone.

C. Claims 16 and 24 stand or fall together.

D. Claims 15, 25 and 26 stand or fall together.

E. Clams 19, 29 and 30 stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the amended brief on appeal filed 11/17/2003 is essentially correct but it contains typing error in the claim 14 wherein the concentration symbols should be indicated as "μmol" or "μg".

The copy of the appealed claims contained in the Appendix to the amended brief on appeal filed 9/10/2001 was/is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

4,379,170	Hettinga et al.	4-1983
5,573,947	Madec et al.	11-1996

10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 U.S.C. § 102

In the instant supplemental examiner's answer Examiner edited and/or added responses to Appellants' arguments with respect to the additional grouping of claims as amended on 11/17/2003.

I. Claims 13-16, 19-21, 24-26, 29 and 30 remain rejected under 35 U.S.C. 102(b) as being anticipated by US 4,379,170.

The claims are directed to a dietary composition comprising propionibacteria at concentration more than 10^9 cells per gram and to a method of making this composition. Some claims are further drawn to incorporation of additional bacteria such as lactic bacteria into the dietary composition. Some claims are further drawn to incorporation of the dietary composition into a food product such as cheese. The propionibacteria in the dietary composition have the capability to produce nitric oxide in physiologically significant quantities *in vivo* to improve intestinal function.

US 4,379,170 teaches a composition comprising propionibacteria and lactic bacteria such as Swiss or Emmental cheeses and a method of making this composition, wherein concentration of propionibacteria in the dietary composition is more than 10^9 cells per gram. For example: see the amounts of the propionibacteria strains P16 and P20 (col. 9, lines 45, 50-52; col. 10, lines 13).

The cited compositions and method of making the compositions are considered to anticipate the claimed invention because the dietary compositions in the cited reference comprise identical amounts (more than 10^9 cells per gram) of identical bacteria (propionibacteria) as required by the claims. And, thus, the compositions of the cited reference which have the identical bacteria in identical amounts may be reasonably considered to inherently possess the ability to produce nitric oxide as required by the claims. Moreover, the cited reference teaches the use of the propionibacteria strain "P20" in a food product or in a method of making food product, for example: cheese. According to appellants' disclosure, the strain P20 has been considered by appellants as capable of producing nitric oxide (see specification page 8, lines 16-20 and page 4, lines 13-15). Therefore, the cited patent appears to anticipate the claimed invention.

A. The argument concerning the Group A, claims 13, 20 and 21, as being anticipated by US 4,379,170 (Hettinga et al.), is rebutted below.

The main appellants' argument (amended brief pages 18-19) is that the cited prior art fails to teach or suggest the ability of propionibacteria to produce nitric oxide (NO). This is not found convincing because both the composition claims and the method claims require the

presence and/or incorporation of the identical bacteria in the same range of concentrations as in the Example 2 of US'170, namely at least 10^9 cells of propionibacteria per gram. The capability of propionibacteria to produce NO is an inherent property of these bacteria regardless of whether or not the production of NO by propionibacteria has been taught or suggested in the prior art.

The propionibacteria in the composition of the cited reference would reasonably be expected to produce physiologically significant quantities of NO, *in vivo*, to effect intestinal function. This is because: 1) the bacterial strain that is present in the cited reference of US'170 (P20) is the same strain that has been shown to be capable of producing NO, *in vitro*, (page 8, lines 16-29 and page 4, lines 13-15); and 2) the results obtained, *in vivo*, are also dependent upon the quantity of the foodstuff consumed. Thus, even a strain, which produces, *in vitro*, a relatively lesser amount of NO than another strains, when consumed in sufficient quantity, would reasonably be expected to be capable of producing sufficient NO to effect intestinal function. The claims are not limited to any specific strain or dosage.

In order to qualify as an anticipatory reference, the disclosure need not express the inherent property. Even failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation: In *Atlas Powder Co. v. IRECO, Inc.*, 51 USPQ2d 1943 (Fed. Cir. 1999). Thus appellants are incorrect in arguing that the anticipatory rejection is improper.

The result or effect of the same procedure by using the same bacterial cultures at the same amount is reasonably expected to be same. See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993). The board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A US patent to Dart disclosed inoculation using *P. cepacia* bacteria for protecting the plant from fungal disease. Dart was silent with regard to nematode inhibition, but the Board concluded that nematode inhibition was an inherent property of the bacteria, and therefore of the method as disclosed by Dart.

Some of the Appellants' arguments are further directed to limitations that are not required by the claims 13, 20 and 21. For example: Appellants argue that the cited method of cheese making as disclosed by US '170 requires the use of some elevated temperature and/or cooking/pasteurizing processes which might result in the killing of propionibacteria, and, thus, the viable amount of propionibacteria would not be capable/sufficient to release NO (amended brief page 18, par. 2). This is not found convincing. Since the ability of producing NO is an inherent property of the propionibacteria of the cited reference, it is considered that the propionibacteria, when present in a viable state, are inherently capable to produce/release NO as intended for the claimed invention. The cited patent US' 170 teaches the use of propionibacteria in the form of viable starter cultures intended for further fermentation and making of a fermented product such as cheese (example 2). The process of example 2 requires a maximum temperature of 124 F in the presence of the propionibacteria. This is a mild temperature, well below pasteurizing temperature of 180 F, and is not considered to be extreme enough to kill the propionibacteria. It is noted that one of appellants' claimed food

products is cheese and that no evidence has been presented that demonstrates that the cheese of Example 2 does not contain at least 10^9 cells of propionibacteria per gram of cheese. In fact, the appellants admit that a mature cheese contains about 10^9 cells/gram of propionibacteria (specification page 2, line 31).

B. The argument concerning the Group B, claim 14, as being anticipated by US 4,379,170 (Hettinga et al.), is rebutted below.

Dependent claim 14, which depends from independent claim 13, is different from claim 13 in that the subject matter of claim 14 encompasses a product obtained by a process but the subject matter of claim 13 is a product. However, the products of both claims 13 and 14 are considered to be identical because the compositions as claimed require only one component that is propionibacteria in amount of 10^9 cells per gram of the composition.

Applicants argue (amended brief, pages 25 and 26) that the cited patent US 4,379,170 does not expressly teach precursor compounds needed for nitric oxide (NO) synthesis such as nitrates or nitrites and, thus, it can not be concluded that the cheese produced accordingly to the described procedure will release in the digestive tract the amounts of Propionibacteria that will produce NO.

However, the amounts of bacterial cells that is claimed and that is described are identical. Therefore, compositions are identical. The mere fact that applicants' bacteria have been harvested, selected or proliferated does not change the end product because the end product is required to contain a particular amount of bacteria but not 5 μmol of NO or 550 μmol/L of nitrate (precursor of NO). Moreover, even though the applicants' bacteria might

have been grown on media with nitrates or nitrites, the volatile, short-live and unstable compound NO that is produced by bacteria is reasonably expected to disappear from the grown/harvested bacteria that are present/incorporated in the final product. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same ... the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP 2113.

The applicants' product is defined by the presence of propionibacteria wherein the capability to produce NO is an inherent feature of the propionibacteria. Thus, the structural characteristics of the presently claimed product and the product of the cited patent are identical. Therefore, claim 14 is properly rejected under 35 U.S.C. 102(b) as being anticipated by US 4,379,170.

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In the instant case, applicants have discovered or demonstrated a new property of propionibacteria such as capability to release NO in the presence of NO precursors. But this capability of propionibacteria has always been an inherent property/function of propionibacteria, regardless the fact whether known or not.

C. The argument concerning the Group C, claims 16 and 24, as being anticipated by US 4,379,170 (Hettinga et al.), is rebutted below.

The difference between the claims of Group A (independent claims 13 and 20) and the claims of Group C (dependent claims 16 and 24 respectively) is that the composition of Group C (claim 16) and method of Group C (claim 24) indicate a list of dietary supplements including both fermented and unfermented preparations. The cited US'170 clearly teaches the presence or incorporation of propionibacteria in either unfermented (starting) preparations or in fermented cheese preparations.

The arguments concerning the lack of disclosure of the inherent capability of propionibacteria to produce physiologically significant amounts of NO to improve intestinal function and to the intended effects of the compositions/methods are repetitive (amended brief pages 39-40) and they have been addressed above.

D. The argument concerning the Group D, claims 15, 25 and 26, as being anticipated by US 4,379,170 (Hettinga et al.), is rebutted below.

The difference between the Group A claims and the Group D claims is that the composition in the claims of Group D indicates a list of products including cheese product, for example. The cited US'170 clearly teaches the presence or incorporation of propionibacteria in fermented products or cheese preparations.

The arguments concerning the lack of disclosure of the inherent capability of propionibacteria to produce physiologically significant amounts of NO to improve intestinal function in the cited reference and to the intended effects of the compositions/methods are repetitive (amended brief pages 32-33) and they have been addressed above.

E. The argument concerning the Group E claims 19, 29 and 30, as being anticipated by US 4,379,170 (Hettinga et al.), is rebutted below.

The difference between the Group E claims and the claims of the other Groups is that the claims of the Group E requires the presence of bifidobacteria and lactobacteria in the compositions and methods of making the compositions. The combined use of bifidobacteria and lactobacteria together with propionibacteria in food compositions and method of making food composition such as cheese, for example, have been known in the art and it has been clearly taught in the cited US'170 (example 2 at col. 10, lines 12-13).

The arguments concerning the lack of disclosure of the inherent capability of propionibacteria to produce physiologically significant amounts of NO to improve intestinal function in the cited reference and to the intended effects of the compositions/methods are repetitive (amended brief pages 46-47) and they have been addressed above.

II. Claims 13-16, 20, 21, 24-26 and 28 remain rejected under 35 U.S.C. 102(b) as being anticipated by US 5,573,947 (Madec et al.).

The claims are directed to a composition and to a method of making this composition comprising propionibacteria at concentration about or more than 10^9 cells per gram of the composition. Some claims are further drawn to composition being food product. The propionibacteria in the dietary composition have the capability to produce nitric oxide in physiologically significant quantities *in vivo* to improve intestinal function.

US 5,573,947 teaches a composition intended for counting viable propionibacteria in various biological samples wherein both the samples and the final compositions inoculated with the samples contain propionibacteria of about or more than 10^9 cells per gram. Some of the disclosed biological samples are Emmental or Morbier cheeses which are taught as containing more than 10^9 CFU/g or more than 10^9 viable cells of propionibacteria per gram (see table 3). Some of the disclosed compositions are compositions comprising medium components and propionibacteria derived from various samples (table 1) wherein the final amount of propionibacteria of about or more than 10^9 cells per gram. The cited patent also discloses a method of making the compositions with propionibacteria by providing a supply of propionibacteria such as a sample of milk or cheese or pure propionibacteria and mixing the supply into various compositions including edible components such as drink (milk) or unfermented preparation (water, milk) or dehydrated preparation (cheese, solid components of the medium) and etc., for example: see col. 5, lines 30-55. The compositions of propionibacteria in the cited patent US'947 and methods of making the compositions in the cited reference are considered to anticipate the claimed invention because both compositions and method of making compositions encompass incorporation of identical components such as propionibacteria at identical amounts such as 10^9 cells per gram. The capability of propionibacteria to produce nitric oxide is an inherent property of propionibacteria. Moreover, the cited reference teaches the use of propionibacteria identified as *Propionibacterium acidipropionici* and *Propionibacterium freudenreichii* strains CNRZ 81, CNRZ 89, CNRZ 277, NCDO 1072, CNRZ 86, CNRZ 80 and LS 2502 (LABO STRADA 2502) (see table 1 at col. 8) which are identical to particular cultures capable of releasing nitric oxide (see

specification page 16, lines 1-10). Thus, the cited patent appears to anticipate the invention as claimed.

A. The argument concerning Group A, claims 13, 20 and 21, as being anticipated by US 5,573,947 (Madec et al.), is rebutted below.

The main appellants' argument (amended brief pages 19-20) is directed to the idea that the cited prior art fails to teach or suggest the ability of propionibacteria to produce nitric oxide (NO). This is not found convincing because both the composition clam 13 and method claims 20 and 21 require the presence or incorporation of the identical bacteria at identical amounts as is disclosed in the composition and method of the cited reference, that is at least 10^9 cells of propionibacteria per gram. The capability of propionibacteria to produce NO is an inherent property of these bacteria, regardless of whether or not the production of NO by propionibacteria has been taught or suggested in the prior art. The bacteria of the compositions would reasonably be expected to inherently express same activity particularly in the light of the fact that the cited compositions and methods comprise incorporation of the identical amounts of propionibacteria. The propionibacteria in the composition of the cited patent US'947 would reasonably be expected to produce physiologically significant quantities of NO, *in vivo*, to effect intestinal function. This is because: 1) the bacterial strains of the cited patent US'947 (see table 1) are identical to the applicants' bacterial strains which have been shown to be capable of producing NO, *in vitro*, (see specification page 16 and Figures 10-12); and 2) the results obtained, *in vivo*, are also dependent upon the quantity of the foodstuff consumed. Thus, even a strain, which produces *in vitro* a relatively lesser amount of NO than another

strains, when consumed in sufficient quantity, would reasonably be expected to be capable of producing sufficient NO to effect intestinal function. The claims are not limited to the use of specific propionibacterial strain or to the protocol of consumption (dosage).

In order to qualify as an anticipatory reference, the disclosure need not express the inherent property. Even failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation: In *Atlas Powder Co. v. IRECO, Inc.*, 51 USPQ2d 1943 (Fed. Cir. 1999). Thus appellants are incorrect in arguing that the anticipatory rejection is improper.

The result or effect of the same procedure by using the same bacterial cultures at the same concentration is reasonably expected to be same. See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993). The board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A US patent to Dart disclosed inoculation using *P. cepacia* bacteria for protecting the plant from fungal disease. Dart was silent with regard to nematode inhibition, but the Board concluded that nematode inhibition was an inherent property of the bacteria, and therefore of the method as disclosed by Dart.

Some of the Appellants' arguments are directed to limitations that are not required by the claims 13, 20 and 21. For example: with regard to the medium composition of US'947 appellants appear to argue that the cited compositions encompass incorporation of some compounds (antibiotics, for example) which might affect viability of the propionibacteria and, thus, the inherent property of the propionibacteria to produce NO (amended brief page 19, last paragraph). However the cited patent US'947 demonstrates that propionibacteria at the same

amount of 10^9 cells per gram as required by the claims have been successfully cultured in the compositions with antibiotics, and, therefore, these propionibacteria are viable and, thus, capable of any and all inherent properties.

B. The argument concerning the Group B, claim 14, as being anticipated by US 5,573,947 (Madec et al.), is rebutted below.

Dependent claim 14 is different from the claim 13 in that it encompasses a product obtained by a process of culturing propionibacteria wherein in the method of culturing the propionibacteria are capable to release 5 μg of nitric oxide after 72 hours on a medium with 550 μmol/l. However, the end product of claim 14 is a composition that requires only one component such as propionibacteria in amount of 10^9 cells per gram of the composition. The applicants' product is defined by the presence of propionibacteria wherein the capability to produce NO is an inherent feature of the propionibacteria. Thus, the structural characteristics of the presently claimed product and the product of the cited patent US'947 (Madec et al.) are identical because both compositions as claimed and as disclosed comprise identical amounts of identical bacteria. Therefore, claim 14 is properly rejected under 35 U.S.C. 102(b) as being anticipated by US 5,573,947.

Appellants' argument that propionibacteria requires NO precursors or nitrogen sources (nitrite or nitrate) in order to be able to produce/release NO (amended brief pages 26-27) is not persuasive because claim 14 does not requires either incorporation of NO precursors nor measuring amounts of NO. Although the claim 14 is directed to a composition wherein the propionibacteria are capable of releasing particular amounts of nitric oxide, if nitrogen source

is available, the claim 14 does not require incorporation of Yeast Extract Lactate (YELA) medium components, including nitrate, into the final dietary composition.

As a matter of fact, the cited patent US '947 (Madec et al.) appears to teach the use of similar "YEL" or "YELA" medium (examples 1-2) for culturing and/or making inoculum of propionibacteria. Thus, the medium that is presently claimed in the method of making the end product as claimed cannot be considered as an inventive approach in culturing propionibacteria over the state of the art. Moreover, the total amount of the NO precursors (nitrate) has to be delineated by the claims to provide for the total effects in NO release as argued.

C. The argument concerning the Group C, claims 16 and 24, as being anticipated by US 5,573,947 (Madec et al.), is rebutted below.

The difference between the claims of Group A (independent claims 13 and 20) and the claims of Group C (dependent claims 16 and 24 respectively) is that the composition of Group C (claim 16) and method of Group C (claim 24) indicate a list of dietary supplements including both fermented and unfermented preparations.

The cited US' '747 (Madec et al.) clearly teaches the presence or incorporation of propionibacteria either in unfermented (starting) preparations medium or in fermented (cheese) preparations.

The arguments concerning the lack of disclosure of the inherent capability of propionibacteria to produce physiologically significant amounts of NO to improve intestinal function and to the intended effects of the compositions/methods are repetitive (amended brief pages 40-42) and they have been addressed above.

D. The argument concerning the Group D claims 15, 25 and 26, as being anticipated by US 5,573,947 (Madec et al.), is rebutted below.

The appellants' arguments concerning inherent property of propionibacteria to produce NO in the composition and method of the cited reference are repetitive (amended brief pages 33-35) and they have been addressed above. The difference between the Group A claims and the Group D claims is the fact that the Group D claims is drawn a propionibacteria composition is in a food product including cheese and milk, for example. The cited US '947 (Madec et al.) teaches the presence or incorporation of the propionibacteria in various dietary products, for example: cheese (table 3) or unpasteurized milk (col. 3, lines 37-39); thus, the claimed composition is anticipated by the cited patent US'947. With regard to other arguments related to viability of the propionibacteria, it is noted that the cited US'947 clearly teaches that the propionibacteria are viable in the dietary compositions such as a final cheese product wherein the propionibacteria are present in amounts of 10^9 cells per gram as required by the claimed invention in order to produce physiologically significant amounts of NO to effect intestinal function (see cheeses Emmental and Morbier, table 3).

For the above reasons, it is believed that the rejections under 35 U.S.C. 102(b) should be sustained.

Respectfully submitted,

Michael G. Wityshyn
Supervisory Patent Examiner
Technology Center 1600

V. Afremova

Examiner Vera Afremova

January 30, 2004.

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600